UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

JOHN HAWKINS,	)	
	)	
Plaintiff,	)	CIVIL ACTION NO.:
v.	)	
	)	
ZIMMER, INC. and	)	JURY TRIAL DEMANDED
ZIMMER HOLDINGS, INC. , n/k/a	)	
ZIMMER BIOMET HOLDINGS, INC.	)	
	)	
Defendants.	)	
_____	)	

COMPLAINT

Plaintiff, JOHN HAWKINS, by and through his counsel, hereby sues ZIMMER, INC. and ZIMMER HOLDINGS, INC., n/k/a ZIMMER BIOMET HOLDINGS, INC. (collectively, referred to as "Zimmer" and/or "Defendants") and alleges as follows:

NATURE OF THE ACTION

1. This is an action for strict products liability, failure to warn, defective design, manufacturing defect, negligence, breach of express and implied warranties, and negligent misrepresentation, brought by JOHN HAWKINS ("Plaintiff") for injuries arising out of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System ("Kinectiv").

2. Defendant Zimmer manufactured and supplied to doctors a dual modular, total hip arthroplasty system known as the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, which was designed to be implanted with either (1) a cobalt-chromium femoral head or (2) a ceramic femoral head.

3. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System utilized with a cobalt-chromium femoral head created an unreasonable risk of harm to Plaintiff.

4. The unreasonable risk of pain, swelling, metallosis, trunnionosis, adverse local tissue reaction, and/or the need for early revision surgical intervention, whether from corrosion, micromotion, fretting or some other mechanism, renders the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System with a metal cobalt-chromium femoral head a defective product.

5. The selection and implantation of the Zimmer M/L Taper with Kinectiv® by Plaintiff's surgeon, Richard A. Berger, M.D., was a result of the misinformation, marketing, sales, promotion and direction by Zimmer.

JURISDICTION & VENUE

6. Plaintiff JOHN HAWKINS is and was at all times relevant, a citizen and resident of State of Illinois.

7. ZIMMER, INC. is and was at all times relevant, a foreign corporation, organized under the laws of Delaware with principal place of business located in Warsaw, Indiana.

8. ZIMMER HOLDINGS, INC. n/k/a ZIMMER BIOMET HOLDINGS, INC. is a foreign corporation organized under the laws of Delaware, with its principal place of business located in Warsaw, Indiana.

9. ZIMMER, INC. and ZIMMER HOLDINGS, INC. n/k/a ZIMMER BIOMET HOLDINGS, INC. are hereinafter collectively referred to as "Zimmer". "Zimmer" includes and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents and representatives and any and all other persons acting on behalf of Defendant ZIMMER, INC. and Defendant ZIMMER HOLDINGS, INC. n/k/a ZIMMER BIOMET HOLDINGS, INC.

10. Zimmer designed, manufactured, fabricated, marketed, packaged, advertised, distributed and sold the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System devices throughout the world, including in Cook County, in the State of Illinois.

11. Zimmer knowingly markets to, and derives income from patients in Cook County, in the State of Illinois, from the sale of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

12. The Defendants acted jointly and severally.

13. The defective Zimmer M/L Taper with Kinectiv® Technology Hip Implant System was implanted into Plaintiff's right hip by Richard A. Berger, M.D. on December 29, 2009 at Rush University Medical Center in Chicago, Illinois. At that time, the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System manufactured, designed, distributed, and warranted by Defendants was implanted into Plaintiff. Plaintiff's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hip replacement surgeries.

14. As a result of his condition, Plaintiff underwent a painful, expensive, and physically risky surgery to remove and replace the defective Zimmer M/L Taper with Kinectiv® Technology Hip Implant System on his right side on April 10, 2017 at Central DuPage Hospital in Winfield, Illinois by William Sterba, M.D.

15. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy between Plaintiff and Defendants exceeds $75,000, exclusive of interest and cost, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

16. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district

ZIMMER M/L TAPER WITH KINECTIV® TECHNOLOGY HIP IMPLANT SYSTEM DEVICE HISTORY

17. ZIMMER, INC., and ZIMMER HOLDINGS, INC. n/k/a ZIMMER BIOMET HOLDINGS, INC., were the designers, manufacturers, and suppliers of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and related components in the business of putting medical devices, including the Kinectiv®, on the market.

18. Zimmer warranted the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and placed the device into the United States stream of commerce.

19. Before it set out to design the dual-modular Zimmer M/L Taper with Kinectiv® Technology Hip Implant System in 2002, Zimmer knew of the danger to human beings if cobalt-chromium metal debris from its products was released into the body through corrosion, micromotion, and/or fretting.

20. Before placing the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System on the market, Zimmer was required to mitigate risks of the product, including any element of the design that created toxic levels of corrosion and debris that could result in pain, swelling, pseudotumor formation, osteolysis, instability, dislocation, metallosis, trunnionosis, adverse tissue reaction and/or the need for early surgical revision in patients-consumers.

21. Despite the knowledge of what might cause corrosion and fretting, the new design Zimmer came up with in the early 2000s and eventually used for the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System called for a neck designed to be thinner in all planes as compared to the M/L Taper.

22. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System neck was/is made of titanium which is more flexible than cobalt-chromium (hereinafter, "CoCr") and was designed to be paired with a dissimilar metal – a CoCr femoral head.

23. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System is designed to be used with a +0 offset head only.

24. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant is part of a modular system that consists of an acetabular component, femoral head, femoral neck, and the instrumentation necessary for implantation of these components. The femoral neck and stem are made from Tivanium® Ti-6Al-4V Alloy. The femoral stem has a porous coating of titanium plasmas spray.

25. The head/neck modular connection of the femoral stem assembly is a 12/14 taper designed to mate with the corresponding bore of a metal or ceramic femoral head component.

26. The changes in design of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, which were different from the M/L Taper include, without limitation: (a) the introduction of a modular neck, increasing flexibility, (b) additional of dual modular junctions, and, (c) variation in the geometry of available components of the neck, both longer and shorter with different angles of version.

27. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System modular neck implants are offered in straight and anteverted/ retroverted designs. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System includes thirty-two titanium neck implants providing sixty head center options: twenty straight, twenty anteverted and twenty retroverted.

28. There are three broad types of modularity: (1) proximal; (2) mid-stem; and (3) distal. Proximal modularity includes head-neck junctions and neck-stem junctions, among others.

29. In a modular neck-stem design, such as the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, there is a "double taper". The resulting junctions are subject to both axial and bending stresses, and others.

30. The dual-modular design of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System doubled the locations where micromotion and fretting can occur, not only at each individual junction, but stemming from the dynamic created by two junctions.

31. The design and selection of material at the dual junctions has an effect on the durability and survivability of the individual component(s) and system as a whole *in vivo.*

32. Zimmer designed, manufactured, promoted, sold and/or marketed the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System to be "implanted in a wide variety of patient types", including, but not limited to: "younger patients; elderly patients; and hip fracture patients". *Zimmer M/L Taper Hip Prosthesis with Kinectiv ® Technology*, 97-7713-001-00 Rev. 2 1012-H16 7.5ML, 2007.

33. For decades, there were concerns in the orthopedic community about employment of this "dual"' modularity. Specifically, it was believed that the additional distal junction of the stem and neck would be a potential site of stem fracture, junction instability and particulate debris generation.

34. Defendants were aware of the problems caused by the increased modularity at the time they designed, manufactured, marketed, distributed and/or sold the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

35. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System taper is a 12/14 size with threading on the taper. This threading can be described as shallow grooves on the portion of the taper that articulates with the head. This threading on the taper is used to comply

with the requirements of the manufacturer of ceramic head option, CeramTec.

36. The significance of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System taper threading is (1) it protects ceramic heads and (2) provides an interface at the junction with a metal head which is much more likely to produce wear and debris under fretting conditions. The threads were not designed to enhance the performance of metal heads.

37. The decision to allow the use of dissimilar metals and a CoCr head (rather solely than a ceramic head) in the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System created an unreasonable risk and made it defective.

38. The concept that that corrosion might occur at the head-neck taper junction of a total hip prosthesis was first described in the early 1980s. When Zimmer was designing the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, with dual modularity, this concept had to be a consideration.

39. Zimmer cleared the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System device, and its related components, under a process used by the United States Food and Drug Administration (hereinafter, "FDA") known as the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device is supposed to demonstrate substantial equivalence to a predicate medical device.

40. The first components of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System were cleared for sale in the United States according to Section 510(k) in January, 2007.

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH THE DUAL MODULAR ZIMMER M/L TAPER WITH KINECTIV® TECHNOLOGY HIP IMPLANT SYSTEM

41. Zimmer marketed its hip implants, including the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, to orthopedic surgeons and hospitals rather than end-user patients.

42. Zimmer had the ability to inform surgeons or hospitals of developing problems or defects in its devices through e-mail, letter, recalls, warnings in product inserts and/or through its product representative(s), who works directly with the surgeon.

43. The mechanical environment of the dual modular junctions place the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System at increased risk for failure from pain, swelling, pseudotumor formation, metallosis, adverse local tissue reaction, synovitis, osteolysis, and/or dislocation, resulting from excessive wear debris, fretting corrosion and recurrent repassivation.

44. The fretting process (mechanical micromotion) is strongly influenced by distribution of pressure and force at the modular junctions, rendering these junctions vulnerable to accelerated generation of metal wear debris and corrosion.

45. Each additional modular interface introduces a contributing source for metal wear particular and debris generation. These junctions exponentially compound and accelerate the wear debris generation process.

46. Corrosion is time-sensitive and accelerated with mechanical stresses. This phenomenon was known to Zimmer, or should have been known by Zimmer, at all times relevant to the design, manufacture, marketing and sale of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

47. At the time of design, manufacture, testing and marketing, Zimmer knew or should have known, combinations of metal alloys at a junction, such as the titanium and cobalt-chromium head-neck junction of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, generate excessive fretting, corrosion and metal wear debris.

48. Zimmer did not inform or warn and is still not informing or warning physicians or consumers either through its sales representatives, correspondence, advertising or package inserts that:

a. Selection of a metal CoCr head rather than a ceramic head to pair with the titanium neck significantly increases the risk of toxic amounts of corrosion and metal debris which might cause pain; swelling; metallosis; trunnionosis; tissue necrosis; adverse local tissue reaction; osteolysis; dislocation; and/or the need for early revision;

b. Zimmer's pre-market corrosion testing only used ceramic heads, not metal CoCr heads with the Kinectiv necks; and/or,

c. Zimmer never performed corrosion testing utilizing both modular junctions at the same time.

49. Zimmer never performed any clinical trials and/or studies prior to marketing the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

50. Zimmer did not fully and/or adequately test the configuration of this new, dual-modular design with two metal-to-metal junctions, utilizing a CoCr femoral head and titanium neck junction, that was implanted into Plaintiff.

51. Although the United States does not have a complete and accurate database which can be used to track problems with hip implants, the Australian Registry can provide information regarding how a product is performing in comparison to other products.

52. According to the Australian registry of devices implanted in Australia between September 1999 – December 2013, comparing the Kinectiv with all other total conventional hip

prostheses, this prosthesis, the Kinectiv, has been identified as having a significantly higher revision rate. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System has a revision rate of 4.6 percent after four years, which is 50% higher than the average revision rate of 2.9 percent for all other hip implants.

53. Zimmer continues to market the CoCr heads for use with the titanium necks in the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

54. Zimmer marketed the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System stating: "[y]ears of extensive engineering design, laboratory testing, testing, and clinical consultation have been devoted to optimizing the structural integrity and junction debris characteristics of the Kinectiv implants. The development and testing of this system not only addressed typical implant performance requirements but criteria exclusive to modular junctions as well. Specifically, these requirements included: 1) Proximal Implant Strength, 2) Fretting/Corrosion, and 3) Junction Stability." In other words, Defendants specifically marketed the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System to alleviate the concerns of doctors and patients who may have heard about fretting and corrosion problems with competitors' hip implant devices. *Performance Evaluation of Kinectiv ® Technology*, S. Meulink, et. al, 2009.

55. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Zimmer's physician/technical consultants, and/or through industry targeted promotional materials.

56. Despite these reassurances, the defective design and manufacture of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, with a CoCr modular femoral head, generates excessive fretting and corrosion occurring at the neck-stem and head-neck taper

junctions. The fretting and corrosion generates toxic metal debris, metal ions and other chemical byproducts which are released into the surrounding tissues. These metal debris, metal ions and byproducts destroy the surrounding tissue and bone, often causing pseudotumors and other metal related conditions. The release of metal debris and metal ions also causes systemic exposure to the toxic metallic elements, often reflected in elevated blood serum and/or urine testing levels.

57. Defendants were aware of the problems caused by dual modularity at the time that they designed, manufactured, marketed, distributed, and/or sold the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System. Nonetheless, Defendants employed the design in its Zimmer M/L Taper with Kinectiv® Technology Hip Implant System in reckless disregard for the safety of patients, including Plaintiff.

58. Moreover, despite direct knowledge of significant adverse events reported by patients and physicians, as well as awareness of failures that have been reported in the literature and published in national Registries, Defendants have continued to market the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System as being safe and effective with the CoCr femoral head.

59. From the time that Defendants first began selling the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System in the United States through today, its product labeling and product information failed to contain adequate information, instructions, and warnings concerning implantation of the product, specifically with the use of a CoCr femoral head, and its increased risks of fretting and corrosion.

PLAINTIFF'S USE OF THE PRODUCT

60. A defectively designed, manufactured and marketed Zimmer M/L Taper with Kinectiv® Technology Hip Implant System left the hands of Defendants in its defective condition,

delivered into the stream of commerce, and was implanted in Plaintiff JOHN HAWKINS's right hip on December 29, 2009 at Rush University Medical Center by Richard A. Berger, M.D. Plaintiff was implanted on the right hip with the following components:

a. Versys® 12/14 Tapered Cobalt-Chromium +0, 32mm femoral head;

b. M/L Taper with Kinectiv® Stem, Size 13.5;

c. M/L Taper with Kinectiv® Neck Implant Size R;

d. Trilogy Acetabular Shell 56mm OD Cluster, and;

e. Longevity® Acetabular Liner XLPE 32mm x 56 mm.

61. As a direct and proximate result of Defendants defective design, manufacture, marketing, distribution, and/or sale of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and placing the defective Device into the stream of commerce, Plaintiff has been injured and damaged as follows:

a. After the implantation of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System Device, Plaintiff initially did well, but developed some pain.

b. Plaintiff subsequently underwent fluid aspiration and blood serum analysis which showed elevated cobalt levels but no evidence of infection.

c. Plaintiff consulted with William Sterba, M.D. on February 23, 2017, at which time Dr. Sterba indicated that the hip implant was failing and causing metal debris to be released from the connection between the head and stem of the implant.

d. Plaintiff, John Hawkin's defective Zimmer M/L Taper with Kinectiv® Technology Hip Implant System suffered from fretting and corrosion causing metals and corrosion byproducts to be released into his bodily tissues surrounding the implant.

e. The release of these metals and corrosion byproducts from the defective Zimmer M/L Taper with Kinectiv® Technology Hip Implant System tissue reaction and/or trunnionosis (pain and physical damage) to Plaintiff's surrounding tissues.

f. As a result of his condition, Plaintiff underwent a painful, expensive, and physically risky surgery to remove and replace the defective Zimmer M/L Taper with Kinectiv® Technology Hip Implant System on his right side on April 10, 2017, at the age of 67 at Central DuPage Hospital, in Winfield, Illinois by William Sterba, M.D.

g. Intraoperative findings included: (1) significant fluid collection, noted most prominently anterior, with also a granulomatous type collection at the medial femur anterior to the lesser trochanter; (2) trunnionosis with grayish debris/fluid noted around the head-neck junction; (3) intact modular neck component; (4) stable femoral and acetabular components with some evidence of lysis present at the more proximal aspect on the femoral side.

62. The mechanism of failure in Plaintiff's device was exactly the same mechanism of failure that Defendants had marketed and warranted would not occur because of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System's design and composition. It was also the same failure mechanism that the medical and scientific community had been studying and documenting in modular device designs since the 1990s,

63. Moreover, the symptoms and findings associated with modular device failures that have been reported in the literature are identical to those suffered by Plaintiff.

64. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings, of the defective Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, Plaintiff has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; physical disability, and past, present and future, medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

THE FDA'S 510(k) CLEARANCE PROCESS

65. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 (hereafter "MDA") of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

66. No clinical testing is required under this process.

67. Subsequent amendments to the MDA allowed for 510(k) clearance for products deemed "substantially equivalent" to post-MDA, 510(k) cleared devices.

68. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

69. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

70. In 2012, at the request of the FDA, the National Institute of Health (hereafter "NIH") conducted a thorough review of the 510(k) process, coming to the following major conclusions:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

71. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices

approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

72. Zimmer cleared the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System device, and its related components, under a process used by the United States Food and Drug Administration known as the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device is supposed to demonstrate substantial equivalence to a predicate medical device.

73. The first components of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System were cleared for sale in the United States according to Section 510(k) in January, 2007.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Strict Products Liability – Defective Design

74. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

75. Defendants are the designers, manufacturers, marketers, advertisers, distributors, sellers, and/or suppliers of orthopedic devices, including the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

76. Defendants are engaged in the business of manufacturing, designing, marketing, advertising, distribution and supplying the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and placed the devices into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

77. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System supplied to Plaintiff was defective in design and formulation and was unreasonably dangerous when it left the hands of Defendants, the manufacturer, designer and supplier, and it reached the user and consumer of the products, Plaintiff, without substantial alteration in which they were sold.

78. Plaintiff is in the class of persons that Defendants should reasonably foresee as being subject to the harm caused by the defectively designed Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, insofar as Plaintiff was the type of person for whom the hip implants were intended to be used.

79. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System had an inadequate design for the purposes of total hip replacement.

80. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System contained unreasonably dangerous design defects, including but not limited to, a femoral neck with dual modular tapers and mixed metal junctions when a Cobalt Chromium femoral head is utilized.

81. The risks associated with the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System when used for its intended and reasonably foreseeable purpose, include but are not limited to: (a) the creation of dangerous and harmful metal debris in the patient's body; (b) pain; (c) mobility inhibition; and (d) likelihood of revision surgery with predictable cascading complications.

82. The Zimmer Kinectiv is defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other hip implants.

83. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System for its intended or reasonably foreseeable purpose.

84. Plaintiff and Plaintiff's healthcare providers could not with the exercise of due care have discovered any defect of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and were reasonable to assume that defendants had 1) performed adequate pre-market testing, and 2) had provided physicians with sufficient education and training to make appropriate and safe medical decisions for patients.

85. Defendants knew or should have known of the defective condition, characteristics, and risks associated with the product.

86. On and prior to Plaintiff JOHN HAWKINS's injuries, the Zimmer Kinectiv Device was defective in design because there existed a reasonable alternative design that would have reduced the risk posed by the subject Kinectiv hip implant system.

87. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

88. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer Kinectiv, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other

damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Strict Products Liability – Failure to Warn

89. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

90. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiff, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

91. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and his prescribing physician, of the true risks of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, including that the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System was susceptible to micromotion, fretting and corrosion at the dual

modular junctions, generating significant and toxic amounts of metal wear debris and corrosive byproducts in patients, causing severe pain and injury, and requiring further treatment, including revision surgery and/or hip replacement.

92. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, or no consumer, including Plaintiff, would have purchased and/or used the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

93. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

94. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System dual modular components and the development of corrosion, metal fatigue, failure, micromotion and/or release of significant amounts of metal debris and/or ions, causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System.

95. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System resulting in revision surgery while knowing that a safer alternative design including, the use of a ceramic femoral head and monoblock stem components existed.

96. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

97. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiff suffered serious and permanent non-economic and economic injuries.

98. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Strict Products Liability – Manufacturing Defect

99. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

100. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, in a condition which rendered it unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

101. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System could fail early in patients therefore giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgery, Defendants continued to market the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System as a safe and effective hip replacement system.

102. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiff suffered harm, damages and economic loss as previously described and will continue to suffer

such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Negligence

103. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

104. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, including a duty to ensure that the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System did not pose a significantly increased risk of bodily injury to its users.

105. Defendants had a duty to exercise reasonable care in the advertising and sale of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, including a duty to warn Plaintiff and other consumers, of the dangers associated with the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System that were known or should have been known to Defendants at the time of the sale of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System to the Plaintiff.

106. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System because Defendants knew or should have known that the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System had a propensity to cause serious injury, including

adverse local tissue reaction, pseudotumor formation, metal debris, corrosion, metal ions, excessive wear, tissue necrosis, pain, swelling, metal ion release, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

107. Defendants failed to exercise ordinary care in the labeling of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff, regarding the risk of serious injury, including, including adverse local tissue reaction, pseudotumor formation, metal debris, corrosion, metal ions, excessive wear, tissue necrosis, pain, swelling, metal ion release, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

108. Defendants knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

109. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances as follows:

a. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising, promotion, inspection, sale and/or distribution of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, and/or to utilize and/or implement reasonably safe designs for them;

b. At all times relevant hereto, Defendants knew or should have known that the unconventional modular design of the Kinectiv was generating the potential for metal on metal problems, vulnerabilities, and injuries;

c. Defendants failed to perform sufficient clinical trials and other pre-marketing evaluations to determine risk and efficacy of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System;

d. Such testing would have revealed the increased risk of failure and tendency to cause significant corrosion, metal wear debris, metal byproduct release, resulting in necrosis, pain, swelling, adverse local tissue

reaction, trunnionosis, and/or metallosis;

e. A reasonable manufacturer under the same or similar circumstances would have conducted additional testing and evaluation of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System before placing it into the stream of commerce;

f. A reasonable manufacturer under the same or similar circumstances would have conducted testing of all junctions coupled with the cobalt-chromium femoral head and evaluation of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System before placing it into the stream of commerce;

g. A reasonable manufacturer under the same or similar circumstances would have required that significant information be provided to physicians regarding the risks associated with foreseeable metal on metal problems stemming from the modular design;

h. At all times relevant hereto, Defendants knew or should have known of the serious complications and high failure rate associated with the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System;

i. Failing to provide adequate and proper warnings to the public and to Plaintiff of the dangerous propensities of Zimmer M/L Taper with Kinectiv® Technology Hip Implant System when used in a reasonably foreseeable manner;

j. Failed to conduct adequate post marketing surveillance;

k. Failing to design, formulate, manufacture and incorporate or to reformulate the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiff when used in a reasonably foreseeable manner;

l. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System in accordance with good design practices;

m. Failing to notify and warn the public including Plaintiff of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, thus misrepresenting the safety of the product;

n. Failing to make timely and adequate corrections to the manufacture, design and formulation of Zimmer M/L Taper with Kinectiv® Technology Hip Implant System so as to prevent and/or minimize the

problems suffered by Zimmer M/L Taper with Kinectiv® Technology Hip Implant System use;

o. Despite its knowledge of these risks, Defendants continued to promote and market the device; and,

p. Being otherwise being careless, reckless and negligent.

110. Despite knowing or having reason to know of the risks, Defendants did not (1) perform additional testing, (2) investigate the risks, (3) suspend sales or distribution, (4) warn physicians or patients of the propensity for the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System to cause or create significant corrosion, metal wear debris, metal byproduct release, resulting in necrosis, pain, swelling, dislocation, osteolysis, pseudotumor formation, adverse local tissue reaction, trunnionosis, metallosis, and/or need for early surgical revision.

111. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and, Plaintiff was implanted with the Zimmer M/L Taper with Kinectiv® Technology Hip Implant Systems and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

112. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and

punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Negligent Misrepresentation

113. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

114. Prior to the Plaintiff receiving the Zimmer Kinectiv, Defendants misrepresented that the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System was a safe and effective total hip replacement system.

115. Defendants failed to disclose material facts regarding the safety and efficacy of the Zimmer M/L Taper with Kinectiv® Technology dual modular hip implant system utilizing a CoCr femoral head, including information regarding increased risk of failure, harmful side-effects, increased risk of revision surgery and lack of adequate testing.

116. Defendants had a duty to provide Plaintiff, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical device they marketed, distributed and sold.

117. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, that their representations regarding Zimmer M/L Taper with Kinectiv® Technology Hip Implant System were false, and that they had a duty to disclose the dangers associated with the device.

118. Plaintiff and his physician reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and material omissions in their marketing, advertisements, and

promotions concerning the quality and safety of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System. Plaintiff and his physicians reasonably relied upon Defendants' representations that the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System was of high quality and safe for implantation into his body.

119. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiff, and the medical community to act in reliance by purchasing the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System with a CoCr femoral head.

120. Defendants' representations and nondisclosures regarding the safety and efficacy of the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System was the direct and proximate cause of Plaintiff's injuries.

121. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Breach of Express Warranty

122. Plaintiff incorporates by reference each and every paragraph of this Complaint as

if fully set forth herein and further alleges as follows:

123. Defendants advertised, labeled, marketed and promoted the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System would conform to the representations. More specifically, Defendants represented that the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's condition.

124. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

125. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System did not conform to the representations made by Defendants in that the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in individuals, such as Plaintiff.

126. At all relevant times, Plaintiff used the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System for the purpose and in the manner intended by Defendants.

127. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

128. The breach of the warranty was a substantial factor in bringing about Plaintiff's

injuries.

129. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and, Plaintiff was implanted with Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
(AGAINST ALL DEFENDANTS)

Breach of Implied Warranty

130. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

131. The Zimmer M/L Taper with Kinectiv® Technology Hip Implant System was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Zimmer M/L Taper with Kinectiv® Technology Hip Implant System minimally safe for its expected purpose.

132. At all relevant times, Plaintiff used the Zimmer M/L Taper with Kinectiv®

Technology Hip Implant System for the purpose and in the manner intended by Defendants.

133. Plaintiff and Plaintiff's physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

134. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

135. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer M/L Taper with Kinectiv® Technology Hip Implant System, Plaintiff was implanted with Zimmer M/L Taper with Kinectiv® Technology Hip Implant System and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

a. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all his injuries and damages, both past and present;

b. Special damages, in excess of the amount required for federal diversity

jurisdiction and in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

c. Double or triple damages as allowed by law;

d. Attorneys' fees, expenses, and costs of this action;

e. Pre-judgment and post-judgment interest in the maximum amount allowed by law;

f. Punitive damages; and,

g. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff JOHN HAWKINS demands a trial by jury on all issues and matters so triable by jury as a matter of right.

Dated: February 15, 2019

Respectfully Submitted,
MEYERS & FLOWERS, LLC.

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